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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/532,719 | 12/20/2005 | Jordi Tormo I Blasco | 5000-0119PUS1 | 8746 |
| 2292 7590 08/21/2007 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747 | | | EXAMINER MURRAY, JEFFREY H | |
| | | | ART UNIT 1624 | PAPER NUMBER |
| | | | NOTIFICATION DATE 08/21/2007 | DELIVERY MODE ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

| | | | |
|------------------------------|-------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/532,719 | Applicant(s) TORMO I BLASCO ET AL. | |
| | Examiner Jeffrey H. Murray | Art Unit 1624 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 1-9, 15, 16 and 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-14 and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>4/25/2005 and 7/19/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. This action is in response to a response to a restriction requirement filed on July 30, 2007. Applicants have elected Group V with traverse. There are eighteen claims pending and six Claims under consideration. Claims 1-9 and 15-16 and 18 are withdrawn from consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. This is the first action on the merits. Claim 10-14 are compound Claims. Claim 17 is a composition Claim. The application relates generally to substituted 6-(2-halogenphenyl)-triazolopyrimidines.

Applicants have traversed the restriction and given arguments as to why the restriction is not proper. These arguments are not found persuasive. Applicants argue that there is a special technical feature between Groups I and V. However, while Groups I and V do share a common core, a triazolopyrimidine with a 2-halophenyl group, there is no special technical feature about the 7-position nitrogen atom. Applicants admit that this nitrogen atom can be bonded to a small, single atom such as hydrogen, or a large 6-membered heterocyclic ring which may be substituted by three radicals. (Claim 10) Such a large variety of residue groups which can affect the compound as a whole based on the possible range of size, polarity, hydrophobicity, etc. of the residue group cannot possibly be considered a common technical feature of the compound or composition.

Applicants also suggest that according to the "Administrative Instructions under PCT" and Annex B Groups VI and VII should be rejoined with Group V. However, once unity of invention has been broken, Groups involving compounds, uses and processes are all grouped into separate categories. Examiner would like to remind applicants that at the end of prosecution,

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Group VII, which is a method Claim, has the possibility of being rejoined with the compound Claims of Group V. The restriction requirement is deemed proper and therefore made FINAL.

Priority

2. Acknowledgment is made of Applicant's claim for foreign priority. This application is a U.S. application 10/532,719, filed December 20, 2005, which is a national stage entry of PCT/EP03/12276, filed November 4, 2003, which claims the benefit of foreign priority to EP 02024808.4, filed November 7, 2002.

Specification

3. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.

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- (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) E SEVERAL VIEWS OF THE DRAWINGBRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF TH (S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

4. The use of the trademark PEROL has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

5. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any of the errors of which applicant may become aware of in the specification.

Claim Rejections - 35 USC § 101

6. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claims 10-14 are rejected under 35 U.S.C. 101 because they claim "compounds" and not a single "compound." Claims must be drawn to a single invention. Examiner suggests replacing

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"compounds" with "compound." Appropriate correction is necessary. No new matter is permitted.

Claim Rejections - 35 USC § 112, 1st

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claim 10-13 and 17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compounds or compositions in which R₁ and R₂ form a 5- or 6-membered nitrogen-containing heterocycle with either zero or one oxygen or sulfur atoms present and L² present on the phenyl ring, does not reasonably provide enablement for all of the compounds and residue groups listed within the Claims, including most of the groups found in R^b. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The test of enablement is whether one skilled in the art could make and use the claimed invention from the disclosures in the application coupled with information known in the art without undue experimentation. (*United States v. Teletronics Inc.*, 8 USPQ2d 1217 (Fed. Cir. 1988)). Whether undue experimentation is needed is not based on a single factor, but rather a conclusion reached by weighing many factors (See *Ex parte Forman* 230 USPQ 546 (Bd. Pat. App. & Inter. 1986) and *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988)).

These factors include the following:

1) *Amount of guidance provided by Applicant.* While the Applicant has demonstrated within the application how to make 6-(2-halogenphenyl)-triazolopyrimidines with a 5- or 6-membered nitrogen containing heterocycle, the generic Claim 10 is massive, and no reference is made as to how to synthesize any compounds that contain a heterocycle with more than one oxygen or sulfur within the ring. Claim 10 also does not describe any compounds containing R^b other than a methyl group.

2) *Unpredictability in the art.* It is well established that "the scope of enablement varies inversely with the degree of unpredictability of the factors involved", and physiological activity is generally considered to be an unpredictable factor. (USPQ 18, 24 (CCPA 1970). See *In re Fisher*, 427 F.2d 833, 839, 166.

Page 3 of the specification demonstrates the first step in synthesizing a compound of Formula I. The first step is a bit vague in that it shows the phenyl ring complete with its substituents already preformed as a malonate ester. On page 26 of the specification, synthetic examples are given. While these are acceptable due to commercially available starting materials, the applicant has not demonstrated or taught how one might synthesize all of the compounds in Claim 10 that contain a R^b group.

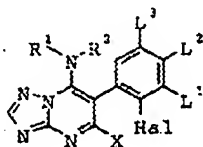
Page 3 of the specification also discusses the second step in the synthetic scheme using either phosphorous oxychloride or phosphorous oxybromide as a reagent. In looking at the potential reactions that could occur when phosphorous oxychloride is present for example, it is seen that numerous side reactions could occur involving many of the potential residue groups of these compounds mentioned in Claim 10. For example, aromatic rings, heterocyclic rings, and

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alkenes, all of which may or are present, can undergo formylation causing the final products formed to not fall under the applicants' claims.

3) *State of the prior art.* While the use in this patent application is for that of an antifungal agent, triazolopyrimidines are currently available drugs for treating depression (antidepressants) such as trazodone; however, tricyclic or similar cyclic anti-depressants have been shown to have side effects such as anticholinergic effects (dry mouth, blurred near vision, constipation, dysuria), antihistamine effects (weight gain, sedation), antiadrenergic effects (postural hypotension, vertigo, dizziness) and cardiotoxicosis or acute poisoning caused by excessive intake. (Nishibe, et. al. US 6,737,085). An individual using such a drug for the purposes of treating fungicides may be exposed and suffer these same side effects.

4) *Scope of the claims.* The scope of the claims involve all of the tens of thousands of compounds of general formula (I):



Thus, the scope of claims is very broad.

5) *Nature of the invention.* The nature of the invention relates generally to substituted 6-(2-halogenphenyl)-triazolopyrimidines, and their use as an antifungal agent.

6) *Level of skill in the art.* The artisan using Applicants invention would be a chemist with a Ph.D. degree, and having several years of experience.

MPEP §2164.01 (a) states, "A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the

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claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)." That conclusion is clearly justified here that Applicant is not enabled for making most of the compounds or compositions mentioned in the current application.

Claim Rejections - 35 USC § 112, 2nd

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 is a dependent Claim of Claim 10. Claim 10 recites, "R¹ and R² together with the interjacent nitrogen atom represent a saturated or partially unsaturated 5- or 6-membered heterocycle..." Claim 11 recites, "Compounds of formula I according to claim 10, in which R¹ and R² together with the interjacent nitrogen atom represent a heterocyclic ring with 5 or 6 carbon atoms..." If Claim 11 contained 6 carbon atoms in addition to the interjacent nitrogen atom, it would be a 7-membered ring and could not depend from Claim 10. Examiner believes that applicants meant to write, "represent a saturated or partially unsaturated 5- or 6-membered heterocycle" in place of "represent a heterocyclic ring with 5 or 6 carbon atoms." Appropriate correction is necessary. No new matter is permitted.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 10-14 and 17 are rejected under 35 U.S.C. 102(a) as being anticipated by Schmitt et. al., WO 2002/002563 which was published on January 10, 2002. The published reference contains numerous compounds which read on the current application. See STN search report registry number 388060-68-2.

14. Claims 10-13 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Pees et. al., US 5,593,996 which was published on January 14, 1997. The published reference contains numerous compounds which read on the current application. See STN search report registry number 187233-45-0.

15. Claims 10-12 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Pfrengle et. al., JP 11035581, which was published on February 9, 1999; and, Pfrengle et. al., U.S. 5,994,360, which was published on November 30, 1999. The published reference contains numerous compounds which read on the current application. See STN search report registry number 220482-09-7.

Double Patenting

16. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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17. Claims 10-14 and 17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claim 1 of U.S. Patent Publication 2007/0078149. Although the conflicting claims are not identical, they are not patentably distinct from each other because Claim 1 of U.S. Patent Publication 2007/0078149 embraces the instant claims 10-14 and 17.

The instant claim differs from the copending claim by a more limited genus than the claim of the copending application. However, it would have been obvious to one having ordinary skill in the art at the time of the invention to select any of the species of the genus of the copending application, including those instantly claimed, because the skilled chemist would have the reasonable expectation that any of the species of the genus would have similar properties and, thus, the same use as taught for the genus as a whole. One of ordinary skill in the art would have been motivated to select the claimed compounds from the genus of the copending application since such compounds would have been suggested by the claims of the copending application. It has been held that a prior art disclosed genus of useful compounds is sufficient to render prima facie obvious a species falling within a genus. *In re Susi*, 440 F.2d 442, 169 USPQ 423, 425 (CCPA 1971), followed by the Federal Circuit in *Merck & Co. v. Biocraft Laboratories*, 847 F.2d 804, 10 USPQ 2d 1843, 1846 (Fed. Cir. 1989).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

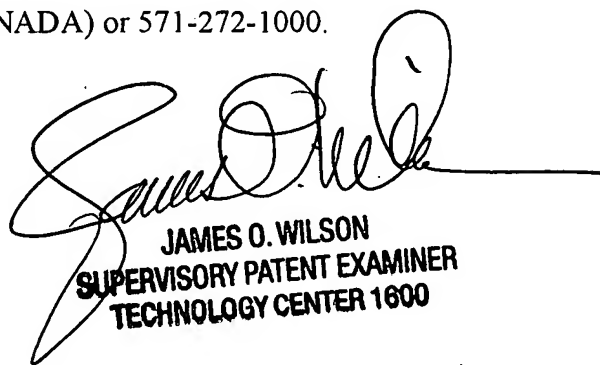
18. Claims 10-14 and 17 are rejected.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey H. Murray whose telephone number is 571-272-9023. The examiner can normally be reached on Mon-Thurs. 7:30-6pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson can be reached at 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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